AMENDED IN ASSEMBLY APRIL 13, 2005 AMENDED IN ASSEMBLY APRIL 5, 2005

CALIFORNIA LEGISLATURE—2005-06 REGULAR SESSION

ASSEMBLY BILL

No. 657

Introduced by Assembly Member Karnette

February 17, 2005

An act to amend Section 4076 of the Business and Professions Code, relating to pharmacies.

LEGISLATIVE COUNSEL'S DIGEST

AB 657, as amended, Karnette. Pharmacies: prescription containers: labels.

The existing Pharmacy Law provides for the licensing, regulation, and enforcement of the practice of pharmacy by the California State Board of Pharmacy. Existing law generally makes it a misdemeanor to knowingly violate the Pharmacy Law.

The Pharmacy Law prohibits a pharmacist from dispensing a prescription except in a container that meets the requirements of state and federal law and is correctly labeled with, among other things, the condition for which the drug was prescribed if requested by the patient and if the condition is indicated on the prescription.

This bill would eliminate the requirement of the labeling requirement pertaining to the condition for which the drug was prescribed, and would instead require the container to be labeled with the intended purpose, as defined, of the drug, if as set forth on the prescription, and would require that the purpose is be listed on the prescription, unless the physician who prescribes the drug or the patient receiving the drug specifically requests that the information be

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omitted. By revising the definition of a crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 4076 of the Business and Professions 2 Code is amended to read:

4076. (a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

- (1) Except where the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or
 - (2) The directions for the use of the drug.
 - (3) The name of the patient or patients.

the principal active ingredients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician

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assistant who functions pursuant to Section 3502.1, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(5) The date of issue.

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- (6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.
 - (7) The strength of the drug or drugs dispensed.
 - (8) The quantity of the drug or drugs dispensed.
- (9) The expiration date of the effectiveness of the drug dispensed.
- (10) The intended purpose of the drug, if the purpose is listed on the prescription, unless the physician who prescribes the drug or the patient receiving the drug specifically requests that the information be omitted.
- (10) The intended purpose of the drug or drugs, if indicated on the prescription. The prescription shall indicate the purpose of the drug or drugs, unless after consulting with the physician and surgeon, the patient requests that the information be omitted. As used in this section, "purpose" means a concise description of the symptom or symptoms that the drug is, or drugs are, intended to treat.
- (11) (A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:
 - (i) Prescriptions dispensed by a veterinarian.
- (ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.
- (iii) Dispensed medications for which no physical description exists in any commercially available database.
 - (B) This paragraph applies to outpatient pharmacies only.
- (C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.
- (D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

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(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

- (c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.
- (d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within his or her scope of practice.
- SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the

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- definition of a crime within the meaning of Section 6 of Article
 XIII B of the California Constitution.